

Stem cell agency commits \$243 million, expands team approach to developing new therapies

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Palo Alto, Calif – The Governing Board of the California Institute for Regenerative Medicine, the state stem cell agency created by proposition 71, today approved the concept for up to \$243 million round of funding to move stem cell-based therapies to clinical trial.

The CIRM Disease Team Awards II will be the second in a recurring round of funding intended to support multidisciplinary teams of researchers working toward filing a request to begin clinical trials to the FDA or completing an early stage trial within four years. This round will support up to twelve awards worth up to \$20 million each.

By funding teams rather than individual researchers, CIRM acknowledges the varied expertise required for translational and clinical research. These teams accelerate progress toward and through clinical trials by preventing duplications in effort and ensuring that the industry translational scientists, clinicians and basic scientists provide complementary expertise. The agency will be actively encouraging industry participation in these awards.

"These teams will drive the promise of Proposition 71 forward by advancing new stem cell therapies towards the clinic, safely—under the pressure of a four-year time table—for a broad range of chronic disease or injury," said Robert Klein, chair of the CIRM Governing Board. "Stem cells hold incredible potential for reducing human suffering. The disease team model combines California's strength in both biotechnology and academic medical science to create world-class teams that could mitigate or cure chronic diseases ranging from diabetes to cancer to acute heart failure or neurodegenerative diseases like Alzheimer's or Parkinson's."

The funded teams will be expected to file a request to begin clinical trials, or to complete phase I or phase II clinical trials by the end of the four-year term.

"The disease team program is integral to our primary strategy of delivering innovative stem cell-associated therapies to patients," said Alan Trounson, CIRM President. "We will be seeking those projects that represent the best possible opportunities for clinical trials."

The Disease Teams II applications will take place in two parts. A lead investigator must first apply for a Disease Team Planning Award of up to \$110,000, which will fund approximately 35 grants to assemble teams, plan and prepare their more elaborate Disease Team application. Only those teams that receive a planning award can submit an application for the full Disease Team award. The RFA will be posted November, 2010.

Recipients of the first round of disease team awards will be able to request approval to expand their projects to include post-IND activities including clinical trials using unspent funds from the original grant.

For public accountability and to obtain an independent evaluation of the performance and standards of the stem cell agency, the board voted to fund an independent assessment by the Institute of Medicine of the National Academies of Science. This study will be paid for out of donor funds contributed to the agency specifically to pay for studies and workshops; it will not utilize taxpayer dollars. The report would have a goal of completion within 22 to 26 months, with recommendations for short-, medium- and long-term actions to improve the performance of the agency.

The board also voted to support Assembly Bill 52 (Portantino), California Umbilical Cord Blood Collection Program, which requests that the University of California establish and administer the Umbilical Cord Blood Collection Program.

About CIRM CIRM was established in November 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure, which provided \$3 billion in funding for stem cell research at California universities and research institutions, was overwhelmingly approved by voters, and called for the establishment of an entity to make grants and provide loans for stem cell research, research facilities, and other vital research opportunities. To date, the CIRM governing board has approved 364 research, training and facility grants totaling more than \$1 billion, making CIRM the largest source of funding for human embryonic stem cell research in the world. Estimates suggest that these grants already awarded will generate tens of thousands of job-years of employment in the state.

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